

JAN 15 2004

510K(k) SUMMARY

K033310 R/L

SUBMITTER: Specialities Remeex International, s.l.
55 Trende Baix
Terrassa Barcelona, Spain 08223

DATE PREPARED: September 10th 2002

DEVICE NAME: Specialities Remeex International, s.l.
Remeex System

CLASSIFICATION NAMES: Mesh, Surgical, Polymeric

PREDICATE DEVICE: Ethicon/Gynecare Pubourethral Sling

Device Description:

The REMEEX SYSTEM (EXternal MEchanical REgulation) is included in the sling techniques for the treatment of urinary incontinence. This system is comprised of a pubourethral sling that permits the patient continence level regulation. This system use a sling, placed under the urethra that can be regulated at any time to get the most adequate bladder neck angle for a particular patient. The sling is connected by traction threads to the prosthesis. The prosthesis is situated over the fascia of the abdominal rectus muscle and is a mechanism that permits the regulation of the sling level.

Predicate Devices:

There has been a device previously cleared by the FDA in the following 510(K) Notification indicated as a pubourethral sling for the treatment of urinary incontinence:

Device	510(k) Document Number	Date Cleared	Indications
Gynecare/ Ethicon Pubourethral Sling	K974098	January 28 th , 1998	Urinary Incontinence

Technologically, both the proposed and predicate devices are the same (i.e. both are meshes that provide pubourethral support) and are indicated for the treatment of urinary incontinence. Additionally, both devices utilize accessories for us in the surgical procedure.

Intended Use:

CONFIDENTIAL

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Intended Use:

REMEEX SYSTEM Indications:

The Remeex System is intended to be used as a pubourethral sling for treatment of female stress urinary incontinence (SUI) resulting from urethral hypomobility or hypermobility and / or intrinsic sphincter deficiency.

Technological Characteristics:

Technologically, both the new device and the predicate device are the same (i.e. both are meshes that provide pubourethral support). Additionally, both devices utilize accessories for use in the surgical procedure. Any differences between the two devices do not raise new questions of safety and effectiveness

Performance Data:

Results of in vitro and clinical evaluations were used to show that the Remeex System functioned as clinically intended. Sufficient data has been gathered from clinical testing to assess that the Remeex System performs as clinically intended

Conclusions:

Based on the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the modified device is substantially equivalent to the existing legally marketed device under the Federal Food, Drug and Cosmetic Act.



JAN 15 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Specialities Remeex International, s.l
c/o Dr. Jeffrey R. Shideman
President
International Medical Products Corporation
7307 Gloucester Drive
Edina, Minnesota 55435

Re: K033310

Trade/Device Name: Specialities Remeex International, s.l. Remeex System
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: December 15, 2003
Received: December 24, 2003

Dear Dr. Shideman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

Miriam C. Provost
for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K033310

510K Notification
Remeex System

Indications for Use:

Specialities Remeex International, s.l. Remeex System

REMEEX SYSTEM Indications:

The Remeex System is intended to be used as a pubourethral sling for treatment of female stress urinary incontinence (SUI) resulting from urethral hypomobility or hypermobility and / or intrinsic sphincter deficiency.

Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☐
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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